

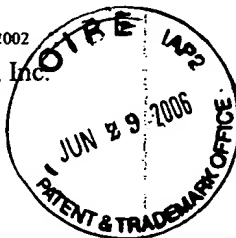


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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,981	01/23/2001	Ejvind Jensen	4343.214-US	2751

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Novo Nordisk North America, Inc.
Suite 6400
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New York, NY 10174-6401



EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

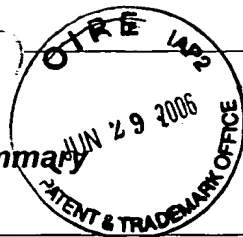
DATE MAILED: 07/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



DOCKET (check off <input checked="" type="checkbox"/>) <input type="checkbox"/>
ATTY: TRAB DCKT 7/30/02

Office Action Summary



Application No.

09/767,981

Applicant(s)

JENSEN ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/860,103.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Notice to comply with the sequence rules.

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**DETAILED ACTION**

Claims 1-14 are pending.

Applicant's election with traverse of group I (claims 1-11), the species phenol, and the species zinc in Paper No. 6 is acknowledged. The traversal is on the ground(s) that in the parent application claims 1-13 were addressed as a single group, therefore there would not be a serious burden on the examiner. This is not found persuasive because addressing the claims in the parent application as a single group does not mean that the search was not or is not a serious burden. Examination of the claims in the parent application does not preclude there being new issues with respect to patentability in the present application and the search burden being compounded by such new patentability issues and the number of inventions examined.

Furthermore, an application may properly be required to be restricted to one of two or more claimed invention if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05(i)). Groups I and II are distinct for the reasons given in the Office action mailed 03/15/2002 (Paper No. 5). Separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a prima facie case that the search and examination of the plural inventions imposes a serious burden upon the Examiner. See M.P.E.P. § 803. Such separate classification is set forth in the Office action mailed 03/15/2002. With respect to group II, applicants can request rejoinder of claims 12, 13 pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), to the extent that claims 12, 13 are directed to the process of making or using a patentable product of group I. In accordance with the Official Gazette notice, *supra*, process

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claims, which do not depend from or otherwise include all the limitations of the allowable product, would NOT been rejoined. With respect to the election of species, upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claims 1-11 are being examined.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following: (a) the application does not contain a copy of the Notice To Comply With Requirements For Patent Maintaining Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Also, the application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because it does not contain the appropriate sequence identifier, i.e., "SEQ ID NO:" at each place where a sequence is disclosed. See the sequence disclosures at page 3, that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and

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(a)(2). This list is not meant to be exhaustive. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application cannot issue until it is in compliance.

5 Correction is required.

Claim 9 is objected to because of the following informalities: "cobalt" is misspelled.

Appropriate correction is required.

10 ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

15 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

20 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for GLP-1, does not reasonably provide enablement for GLP-1 compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these
25 claims. The specification intends the term "GLP-1 compounds" to encompass analogs and functional derivatives of GLP-1 (sentence bridging pages 1-2). Other than GLP-1, the specification fails to provide guidance for making, and working examples of, GLP-1 compounds.

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Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (v7) page 1306, column 1, full paragraph 1, or Ngo (w7) page 433, full paragraph 1, and
5 page 492, full paragraph 2. The skilled artisan is left to extensive, random, trial and error experimentation in order to obtain such GLP-1 compounds other than GLP-1. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation
10 for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had
15 possession of the claimed invention. The claims are directed to or encompass a "GLP-1 compound". The specification intends the term "GLP-1 compounds" to encompass analogs and functional derivatives of GLP-1 (sentence bridging pages 1-2). These are genus claims. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid
20 substitutions, deletions, insertions and/or additions that may be made to GLP-1. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although

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these types of changes are routinely done in the art, the specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, GLP-1 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus.

Thus, applicant was not in possession of the claimed genus:

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising GLP-1 wherein the composition is a thixotropic gel, does not reasonably provide enablement for said composition wherein the thixotropic property only or mainly results from GLP-1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification discloses that compositions comprising GLP-1 and a phenolic compound form thixotropic gels (page 3, first paragraph). The claim is directed to a composition comprising GLP-1 wherein the composition is a thixotropic gel, wherein the thixotropic property only or mainly results from GLP-1. The metes and bounds of “mainly” are not clearly set forth, as discussed below. The terms “only” and/or “mainly” imply or encompass a thixotropic composition wherein the only active

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ingredient is GLP-1. All of the working examples wherein a thixotropic gel is formed contain GLP-1 and a phenolic compound or GLP-1, a phenolic compound, and zinc. The specification fails to describe, or provide guidance for making, a thixotropic composition comprising wherein the thixotropic property only or mainly results from GLP-1. The skilled artisan is left to undue experimentation in order to determine how to form a composition comprising GLP-1 wherein the composition is a thixotropic gel, wherein the thixotropic property only or mainly results from GLP-1. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The "certain concentrations" of the compositions ingredients, critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification discloses that compositions comprising GLP-1 and a phenolic compound in "certain" concentrations form thixotropic gels (page 3, first paragraph). All of the working examples wherein a thixotropic gel is formed contain GLP-1 and a phenolic compound or GLP-1, a phenolic compound, and zinc in "certain" concentrations but these concentrations are not included in the claims.

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The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 11 are indefinite because the Markush groups are recited in an improper Markush format and the claims are ambiguous. The metes and bounds are not clearly set forth. When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper. See M.P.E.P. 2173.05(h). It is suggested that materials so related as to constitute a proper Markush group, be recited in the conventional manner, or alternatively.

Claims 7, 8 recite the limitation "wherein the thixotropic property". There is a lack of antecedent basis for this limitation in the claims. The metes and bounds are not clearly set forth.

Regarding claims 3, 6, 9, 11, the phrases "e.g.", "preferably", "more preferably", and "most preferably" render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). The metes and bounds are not clearly set forth.

Claims 1, 3-11 are indefinite because they recite the term "gel" (claim 1). The instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "gel". There is no single art recognized definition for the term "gel". See Nairn (u7), page 1539, column 2, full paragraph 2. An artisan cannot determine what

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additional or material functional limitations are placed upon a claim by the presence of this element.

Claim 11 is indefinite over the recitation of "between 0.2 and above 0.1" because the metes and bounds of the range are not clearly set forth. It is suggested that the claim recite

5 "between 0.2 and 0.1".

Claims 1-11 are indefinite because they recite the term "GLP-1 compound". Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "GLP-1" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and
10 bounds are not clearly set forth.

The term "mainly" in claims 7, 8 is a relative term which renders the claim indefinite. The term "mainly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

15

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

20 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Danley (4, cited by Applicants) in view of Nairn (u7) and Ballard (x7).

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Danley teaches a low solubility form of GLP-1(7-37) prepared by combining GLP-1(7-37) at from 2-15 mg/ml in buffer at pH 7-8.5 with a solution of a metal ion salt to obtain solutions with from 1-8 mg/ml GLP-1(7-37) at molar ratios of about 1:1 to 270:1 zinc to GLP-1(7-37) (page 35, Example 34). 8 mg/ml GLP-1(7-37) is not less than about 2 mg/ml, not less
5 than about 5 mg/ml, not less than about 10 mg/ml, or not more than about 100 mg/ml of a GLP-1 compound.

Danley teaches compositions comprising GLP-1(7-37) (page 12, line 57, through page 14, line 4), a phenolic compound, and zinc (page 14, lines 6-9) wherein the phenolic compound is phenol (page 19, line 5), wherein the molar ratio of zinc to GLP-1(7-37) is 0.1 to 6 (page 19,
10 lines 5-6), wherein the aqueous media is a pharmaceutically acceptable carrier (page 19, lines 1-2), wherein the composition contains 4 mg/ml of the insulinotropic compound (Example 21, page 28). 4 mg/ml GLP-1(7-37) is not less than about 2 mg/ml, not less than about 5 mg/ml, not less than about 10 mg/ml, or not more than about 100 mg/ml of a GLP-1 compound.

Danley teaches amorphous and microcrystalline compositions comprising 9.5 mg/ml
15 GLP-1(7-37) (page 37, Table 3). 9.5 mg/ml GLP-1(7-37) is not less than about 2 mg/ml, not less than about 5 mg/ml, not less than about 10 mg/ml, or not more than about 100 mg/ml of a GLP-1 compound.

Although Danley is silent with respect to the composition being a gel, the present

20 ^{rel 7} specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "gel", and there is no single art recognized definition for the term "gel". See Nairns (u7), page 1539, column 2, full paragraph 2. Furthermore, a composition has thixotropic properties when it becomes more fluid in its consistency and flows more readily

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when it is shaken or stirred vigorously than when it stands for some time. See Ballard (x7) at page 1610, right column, last full paragraph. Danley's compositions become more fluid in their consistency and flow more readily when they are shaken or stirred vigorously than when they stand for some time, in the absence of evidence to the contrary, because no difference is seen between Danley's compositions comprising a GLP-1 compound and zinc or a GLP-1 compound, phenol and zinc, and the claimed compositions. The thixotropic properties of such compositions only or mainly result from the presence of the GLP-1 compound, in the absence of evidence to the contrary. Danley's composition has all the ingredients of the claimed composition. A chemical composition and its properties are inseparable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over {Danley (4, cited by Applicants) in view of Nairns (u7) and Ballard (x7)} and further in view of Galloway (a13), Schott (y7), and Ballard (x7).

Danley teaches a low solubility form of GLP-1(7-37) prepared by combining GLP-1(7-37) at from 2-15 mg/ml in buffer at pH 7-8.5 with a solution of a metal ion salt to obtain solutions with from 1-8 mg/ml GLP-1(7-37) at molar ratios of about 1:1 to 270:1 zinc to GLP-1(7-37) (page 35, Example 34). 8 mg/ml GLP-1(7-37) is not less than about 2 mg/ml, not less

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than about 5 mg/ml, not less than about 10 mg/ml, or not more than about 100 mg/ml of a GLP-1 compound.

Danley teaches compositions comprising GLP-1(7-37) (page 12, line 57, through page 14, line 4), a phenolic compound, and zinc (page 14, lines 6-9) wherein the phenolic compound is phenol (page 19, line 5), wherein the molar ratio of zinc to GLP-1(7-37) is 0.1 to 6 (page 19, lines 5-6), wherein the aqueous media is a pharmaceutically acceptable carrier (page 19, lines 1-2), wherein the composition contains 4 mg/ml of the insulinotropic compound (Example 21, page 28). 4 mg/ml GLP-1(7-37) is not less than about 2 mg/ml, not less than about 5 mg/ml, not less than about 10 mg/ml, or not more than about 100 mg/ml of a GLP-1 compound.

Danley teaches amorphous and microcrystalline compositions comprising 9.5 mg/ml GLP-1(7-37) (page 37, Table 3). 9.5 mg/ml GLP-1(7-37) is not less than about 2 mg/ml, not less than about 5 mg/ml, not less than about 10 mg/ml, or not more than about 100 mg/ml of a GLP-1 compound.

Although Danley is silent with respect to the composition being a gel, the present specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "gel", and there is no single art recognized definition for the term "gel". See Nairns (u7), page 1539, column 2, full paragraph 2. Furthermore, a composition has thixotropic properties when it becomes more fluid in its consistency and flows more readily when it is shaken or stirred vigorously than when it stands for some time. See Ballard (x7) at page 1610, right column, last full paragraph. Danley's compositions become more fluid in their consistency and flow more readily when they are shaken or stirred vigorously than when they stand for some time, in the absence of evidence to the contrary, because no difference is seen

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between Danley's compositions comprising a GLP-1 compound and zinc or a GLP-1 compound, phenol and zinc, and the claimed compositions. The thixotropic properties of such compositions only or mainly result from the presence of the GLP-1 compound, in the absence of evidence to the contrary. Danley's composition has all the ingredients of the claimed composition. A chemical composition and its properties are inseparable.

see 112
first para
of claim

This rejection is being made in the event that the rejection under 35 U.S.C. 102(b) as being anticipated by Danley is overcome. Danley is silent with respect to the composition being a thixotropic gel.

Galloway teaches that only a small quantity of zinc is required to complex with and precipitate a significant portion of the GLP-1 molecules (column 12, lines 23-25).

Schott teaches that thixotropy is particularly useful in the formulation of pharmaceutical suspensions and emulsions; thixotropy can be used to solve the dilemma involving low viscosity and rapid settling of solid particles in suspensions and rapid creaming of emulsions; thixotropy prevents sedimentation and claying of suspended particles; Schott also teaches thixotropic agents (page 318, column 1, full paragraph 1).

Ballard gives a clear indication of success in designing a sustained- or prolonged-action preparation with thixotropic "pellets" and teaches the advantages thereof. See Ballard page 1610, column 1, first paragraph, and column 2, full paragraphs 1-3.

Galloway, Schott, and Ballard do not teach a thixotropic composition comprising GLP-1. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make a composition comprising GLP-1 and a phenolic compound or a composition comprising GLP-1, a phenolic compound, and zinc, as taught by Danley, and to modify that

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teaching by making a thixotropic composition, as taught by Schott and/or Ballard, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because only a small quantity of zinc is required to complex with and precipitate a significant portion of GLP-1 and a thixotropic composition would prevent sedimentation and claying of the precipitated GLP-1 particles. When the suspension is shaken prior to use it becomes fluid enough to pass through a hypodermic needle. The invention is prima facie obvious over the prior art.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
JULY 14, 2002